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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,024	11/24/2003	Grace Jones	50229-420	9113

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EXAMINER	
SHAFER, SHULAMITH H	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,024	JONES ET AL.	
	Examiner	Art Unit	
	Shulamith H. Shafer, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim(s) 1-21, drawn to nucleic acids, classified in class 536, subclass 23.4, 23.5, 24.1.

II. Claim(s) 22 and 23, drawn to proteins, classified in class 530, subclass 350.

III. Claim(s) 24, and 25 drawn to a method of identifying ligands of nuclear hormone receptors, classified in class 435, subclass 7.1.

IV. Claim(s) 26-29, drawn to a nuclear hormone receptor response element, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because groups I, II, and IV constitute three patentably distinct inventions for the following reasons.

Inventions I, II, and IV are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct.

The polynucleotides of Group I, and IV and the polypeptides of Group II are patentably distinct for the following reasons: polynucleotides, which are composed of purine and pyrimidine units and polypeptides, which are composed of amino acids, are structurally distinct molecules; any relationship between a polypeptide and polynucleotide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Further, the polypeptides of Invention II can be prepared by processes which are materially different from the nucleic acids of Group I, such as chemical synthesis, or by isolation and purification from natural sources. The nucleic

acids of Invention I can be used other than to make the polypeptides of Invention II, such as in gene therapy or a probe in nucleic acid hybridization assays. Furthermore, searching the inventions of Groups I and IV, (polynucleotides) and Group II (proteins) together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides is not coextensive.

Inventions I and IV are directed to polynucleotides, but these are all distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Invention I is directed to isolated nucleic acids encoding for nuclear hormone receptors; Invention IV is directed to a nuclear hormone response element. These two inventions have distinct functions and have acquired a separate status in the art because of separate search requirements and different classification. The search for these two inventions would not be coextensive and would represent a serious burden to the examiner and the resources of the USPTO.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Invention I can be used for purposes other than the screening methods of Invention III. The polynucleotides can be used in hybridization experiments.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Invention II can be used for purposes other than the screening methods of Invention III. The proteins can be used to generate antibodies.

The methods of Invention III and the nuclear hormone receptor response element of Invention IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Invention III do not make or recite utilization of the products of Invention IV.

The methods of Invention III and the nuclear hormone receptor response element of Invention IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Invention III do not make or recite utilization of the products of Invention IV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements and different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

If applicants elect Inventions I, II or III Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from **A-J** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

This application contains claims directed to the following patentably distinct species of the claimed invention: Sequences.

A. An isolated nucleic acid encoding a protein:
   i. having a tryptophan residue in 1st position corresponding to position 477 of SEQ ID NO:2 and a tryptophan residue in a 2nd position corresponding to position 479 of SEQ ID NO:2; or
   ii. having a tryptophan residue in a 1st position corresponding to position 477 of SEQ ID NO:2; or
   iii. having a tryptophan residue in a 1st position corresponding to position 479 of SEQ ID NO:2

B. An isolated nucleic acid encoding a protein having a tryptophan residue in a 1st position corresponding to position 302 of SEQ ID NO:2

C. An isolated nucleic acid encoding a protein having a tryptophan residue in 1st position corresponding to position 315 of SEQ ID NO:2

D. An isolated nucleic acid encoding a protein:
   a. having a phenylalanine residue in a 1st position corresponding to position 318 of SEQ ID NO:2; or
   b. having a phenylalanine residue in a 1st position corresponding to position 328 of SEQ ID NO:2; or
   c. having a phenylalanine residue in a 1st position corresponding to position 318 of SEQ ID NO:2 and a phenylalanine residue in a 2nd position corresponding to position 328 of SEQ ID NO:2

E. An isolated nucleic acid encoding a protein:
   1. having a tryptophan residue in a 1st position corresponding to position 498 of SEQ ID NO:2, a tryptophan residue in a 2nd position corresponding to

position 499 of SEQ ID NO:2 and phenylalanine residue in a 3rd position corresponding to position 318 of SEQ ID NO:2

2. having a tryptophan residue in a 1st position corresponding to position 498 of SEQ ID NO:2, a tryptophan residue in a 2nd position corresponding to position 499 of SEQ ID NO:2 and phenylalanine residue in a 3rd position corresponding to position 328 of SEQ ID NO:2
3. having a tryptophan residue in a 1st position corresponding to position 498 of SEQ ID NO:2, a tryptophan residue in a 2nd position corresponding to position 499 of SEQ ID NO:2 and phenylalanine residue in a 3rd position corresponding to position 318 of SEQ ID NO:2 and a phenylalanine residue in a 4th position corresponding to position 328 of SEQ ID NO:2
4. having a phenylalanine residue in a 1st position corresponding to position 318 of SEQ ID NO:2
5. having a phenylalanine residue in a 1st position corresponding to position 318 of SEQ ID NO:2, and a phenylalanine residue in a 2nd position corresponding to position 328 of SEQ ID NO:2

F. An isolated nucleic acid encoding a protein having an alanine residue in a 1st position corresponding to position 472 of SEQ ID NO:2 and leusine residue in a second position corresponding to position 475 of SEQ ID NO:2

G. An isolated nucleic acid encoding a protein having an arginine residue in a position corresponding to position 302 of SEQ ID NO:2

H. An isolated nucleic acid encoding a protein having an arginine residue in a 1st position corresponding to position 293 of SEQ ID NO:2

I. An isolated nucleic acid encoding a protein having an arginine residue in a 1st position corresponding to position 288 of SEQ ID NO:2

J. An isolated nucleic acid encoding a protein:

i. having an alanine residue in a 1st position corresponding to position 366 of SEQ ID NO:2

ii. having an alanine residue in a 1st position corresponding to position 366 of SEQ ID NO:2 and an alanine residue in a 2nd position corresponding to position 288 of SEQ ID NO:2

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from **A-J** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If applicants elect Invention IV, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from **1-2** (DR sequences) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

This application contains claims directed to the following patentably distinct species of the claimed invention: DR Sequences:

1. SEQ ID NO:8

2. SEQ ID NO:9

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of DR sequences,**1 or 2,** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If applicants elect Invention IV, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from **a-e** (Promoter sequences) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable

This application contains claims directed to the following patentably distinct species of the claimed invention: Promoter Sequences:

a. SEQ ID NO:3
b. SEQ ID NO:4
c. SEQ ID NO:5

d. SEQ ID NO:6

e. SEQ ID NO:22

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of Promoter sequences, **a-e,** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shulamith H. Shafer, Ph.D. whose telephone number is 571-272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph.D. can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHS